EXHIBIT 39

CONFIDENTIAL — SUBJECT TO PROTECTIVE ORDER

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	
	)	MDL No. 2804
This document relates to:	)	
	)	Case No. 17-md-2804
The County of Cuyahoga v. Purdue Pharma L.P., et al., Case No. 17-OP-45004 (N.D. Ohio)	)	Hon. Dan Aaron Polster
The County of Summit, Ohio, et al. v. Purdue Pharma L.P. et al., Case No. 18-OP-45090 (N.D. Ohio)	)	

REPORT OF KARL C. COLDER

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A. Illegal street opioids, most notably heroin and fentanyl, were and are DEA's primary focus during the opioid abuse crisis. 50

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also my job to manage the Washington Field Division's budget. In doing so, I regularly drafted proposals outlining how DEA should use its limited resources to fight the opioid abuse crisis in my region. Although I occupied a senior leadership position, I took pride in engaging with constituents of the communities I served, which allowed me to better understand their problems and work together to develop solutions. For example, as part of the DEA 360 Strategy, I engaged with community leaders, registrants, and law enforcement in West Virginia to identify strategies to fight the opioid abuse crisis plaguing that state.

6. Education

Prior to joining DEA, I received a B.A. in Political Science in 1983 and a B.A. in Social Relations/Criminal Justice in 1984, both from Cheyney University of Pennsylvania. In 2009, I earned a Master's Degree in Human Resources Development and Training from Seton Hall University.

7. Professional and Community Affiliations

I hold (or formerly held) several positions in professional and community organizations, including the following:

- National Association of Black Narcotics Agents (*Former National President*)
- Metropolitan Washington Council of Governments Substance Dependency Program (*Chairman of Executive Planning Committee*)
- Baltimore/Washington and Appalachia High Intensity Drug Trafficking Area Task Force (*Executive Committee Chairman*)
- Episcopal Church Province 3 Opioid Abuse Task Force (*Co-Chair*)

pharmaceutical-wholesaler-value-drug-inc-pay-4000000; Press Release, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act*, Justice Department Documents and Publications (Dec. 23, 2016), *available at* https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act; *Feds: McKesson agrees to pay $150M in pill shipment case*, U.S. News & World Report (Jan. 17, 2017), *available at* https://www.usnews.com/news/business/articles/2017-01-17/feds-mckesson-agrees-to-pay-150m-in-pill-shipment-case.

B. Retention and Scope of Work

I understand that Allergan Finance, LLC, Allergan plc, Allergan Sales, LLC, Allergan USA, Inc., Actavis Pharma, Inc., Actavis LLC, Watson Laboratories, Inc., Cephalon, Inc., Teva Pharmaceuticals USA, Inc., and others, have been sued by a number of plaintiffs in *In re: National Prescription Opiate Litigation* (MDL No. 2804). I have been retained to provide expert opinions on behalf of Allergan Finance, LLC, as well as Teva and Actavis Generics defendants, on the following topics:

- Knowledge of the DEA's interpretation and enforcement of 21 U.S.C. § 823 and 21 C.F.R. §1301.74;
- Knowledge of communications with DEA registrants, generally, whether written or oral, regarding their obligations under 21 C.F.R. §1301.74;
- DEA practices and procedures relating to the use of ARCOS data to combat diversion;
- Knowledge of the DEA's efforts to combat illicit opioid markets and illicit opioids; and
- Knowledge of DEA initiatives and work performed to combat the opioid abuse crisis, including community engagement, diversion training, and enforcement.

I am being compensated at my usual rate of $300 per hour, plus reasonable expenses. My compensation is in no way based on the outcome of this litigation or on the content of my opinions or testimony.

C. Introduction

DEA's mission is to "enforce the controlled substances laws and regulations of the United States." [4] The Controlled Substances Act ("CSA")—which is enforced and administered principally by DEA—uses the concept of registration to bestow legal authority to handle controlled substances. [5] Under Section 822 of the CSA, manufacturers and distributors of controlled substances are required to register with DEA: "Every person who manufactures or distributes any controlled substance, or who proposes to engage in the manufacture or distribution of any

[4] DEA Website: Mission Statement, *available at* https://www.dea.gov/mission.

[5] *See* 21 U.S.C. § 801 *et. seq.*

controlled substance or list I chemical shall obtain annually a registration . . ."[6] Section 823 of the CSA sets forth factors to be considered by DEA prior to issuing a registration, which includes, among other things, that the registrant maintain "effective controls against diversion . . ."[7] If DEA determines that a registrant is not in compliance with the CSA, DEA has authority to revoke or suspend its registration, pursue administrative enforcement actions (*e.g.*, Letter of Admonition, Informal Administrative Hearing, Order to Show Cause), and to seek civil fines or criminal penalties in federal district court.[8]

DEA is also tasked with setting quotas—both in the aggregate and at the individual manufacturer level—for controlled substances.[9] By including the quota system in the CSA, Congress intended to "reduce or eliminate diversion."[10] Indeed, the purpose of quotas "are to provide for the adequate and uninterrupted supply for legitimate medical need of the types of schedule I and II controlled substances that have a potential for abuse, while limiting the amounts available to prevent diversion."[11]

D. Summary of Opinions

Based on my analysis—which has been informed by my 32 years of experience at DEA and my review of the materials cited throughout this report and in Exhibit B—I have formed the

[6] *See* 21 U.S.C. § 822(a)(1).
[7] *See* 21 U.S.C. § 823(a)(1).
[8] *See* 21 U.S.C. § 801 *et. seq;* Rubin, Paul D., et al, "*Chapter 23: Compliance with DEA Controlled Substance Requirements*," PLI, Health Care Mergers and Acquisitions Answer Book (2018); Gilbert, John A. & Houchk, Larry K., "*Chapter 17: Controlled Substances*," FDA Deskbook: A Compliance and Enforcement Guide (2018).
[9] *See* 21 U.S.C. § 826; 21 C.F.R. Part 1303.
[10] *See* Press Release, *DEA Reduces Amount Of Opioid Controlled Substances To Be Manufactured In 2017*, DEA (Oct. 4, 2016), *available at* https://www.dea.gov/press-releases/2016/10/04/dea-reduces-amount-opioid-controlled-substances-be-manufactured-2017.
[11] *Id.; see also* Apr. 11, 2019 Dep. of Stacy Harper-Avilla at 47:9-13 ("Q. What is the -- is it fair to say that one of the purposes of granting procurement quota is to ensure an adequate and uninterrupted supply of medications? A. It is one purpose.").

opinions described in this report to a reasonable degree of certainty. In general, those opinions include the following:

- DEA's suspicious order monitoring regulation and guidance is and has been vague and subjective, leaving registrants with significant discretion in creating their suspicious order monitoring systems.
- DEA did not provide meaningful guidance to registrants seeking more information on how to comply with their suspicious order monitoring obligations, leaving interpretation to the discretion of individual registrants.
- The claims of James E. Rafalski and Dr. Seth B. Whitelaw (two individuals retained by Track One Plaintiffs) that a compliant suspicious order monitoring system requires specific components has no basis in regulation and is inconsistent with DEA practice.
- If a company received no notification, action, or warning from DEA related to their suspicious order monitoring system even after regular audits, the registrant could expect that DEA did not find any violations of the relevant suspicious order monitoring laws and regulations.
- DEA's failure to allocate sufficient resources to the geographic areas in greatest need contributed to the growth of the opioid abuse crisis.
- DEA could have better responded to the opioid abuse crisis by allocating its resources in a more balanced manner across enforcement, diversion control, and community engagement.
- DEA did not effectively use its exclusive access to complete, aggregated ARCOS data to combat the opioid abuse crisis.
- DEA did not effectively utilize suspicious order reports submitted by registrants to identify targets contributing to the growth of the opioid abuse crisis.
- Illegal street opioids, most notably heroin and fentanyl, were and are DEA's primary focus during the opioid abuse crisis.
- Illicit sources for prescription opioids—such as pills mills, internet pharmacies, and doctor shopping—were and are a major cause of the opioid abuse crisis.[12]

II. DEA'S SUSPICIOUS ORDER MONITORING REGULATION AND RELATED GUIDANCE IS VAGUE AND SUBJECTIVE, LEAVING REGISTRANTS WITH SIGNIFICANT DISCRETION IN CREATING A COMPLIANT SUSPICIOUS ORDER MONITORING SYSTEM.

Among other things, the CSA creates a closed regulatory system that establishes strict controls over the manufacture, distribution, dispensing, or possession of controlled substances.[13]

[12] I reserve the right to amend or supplement this report based on any additional information that is brought to my attention, including, but not limited to, information from documents, expert reports, or testimony. If called to testify, I may use summaries and demonstratives (prepared and disclosed pursuant to the Court's scheduling orders) to assist my testimony.

[13] *See* 21 U.S.C. § 801 *et. seq.*

A person or entity must register with the DEA in order to become a part of this closed system.[14] The Attorney General is granted the authority to register an applicant to manufacture Schedule I or II controlled substances "if he determines that such registration is consistent with the public interest[.]"[15] In determining the public interest, the statute lists several factors to be considered, including:

> "maintenance of effective controls against diversion of particular controlled substances … into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes[.]"[16]

The implementing federal regulation that addresses suspicious order monitoring has remained the same since it was promulgated in 1971:

> "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[17]

The DEA has issued some guidance about how to interpret the suspicious order monitoring regulation through formal letters provided to registrants,[18] presentations to individual companies at distributor briefings,[19] and presentations to registrants at industry conferences.[20] The DEA also provided guidance to Diversion Investigators about how to apply the CSA and federal

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14 *See* 21 U.S.C. § 822.
15 *See* 21 U.S.C. § 823(a).
16 *See* 21 U.S.C. § 823(a)(1).
17 *See* 21 C.F.R. § 1301.74(b).
18 *See, e.g.*, ALLERGAN_MDL_02467796 (the "2006 Dear Registrant Letter"); ALLERGAN_MDL_02187202 (the "2007 Dear Registrant Letter").
19 *See, e.g.*, US-DEA-00000143; US-DEA-00000588; US-DEA-00000214; US-DEA-00000367; US-DEA-00000368; US-DEA-00000378; US-DEA-00000386; US-DEA-00000404; US-DEA-00000469; US-DEA-00000933; US-DEA-00001043.
20 *See, e.g.*, DEA Presentation: *Effective Controls Against Diversion*, Manufacturer/Importer/Exporter Conferences (2013), *available at* https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2013/arnold.pdf; and DEA Presentation: *Manufacturer Trends & Updates*, Manufacturer Conference (2015), *available at* https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2015/prevoznik.pdf.

regulation through the Diversion Investigators' Manual.[21] Additionally, the DEA provided guidance to its Diversion Program Managers, Group Supervisors, and Senior Diversion Investigators through OD Policy Letters issued by the DEA Headquarters Office of Diversion Control.[22]

In my role as Special Agent in Charge, I managed the overall functions of the Washington Field Division, including its Diversion Control Program, under which pharmaceutical manufacturers, pharmacists, and medical practitioners are registered, monitored, and audited. I oversaw our Diversion Control Program through the day-to-day management of our Diversion Program Manager. I was also involved in settlements with distributors and pharmacies related to suspicious order monitoring.[23]

In reaching the opinions set forth below related to suspicious order monitoring, I relied on DEA's regulations and general guidance letters, as well as my own experience (described in greater detail in Section I(A) and Exhibit A).

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[21] *See, e.g.*, CAH_MDL2804_02203353 at -3355 *et. seq.* (1996); CAH_MDL2804_02145395 at -5399 *et. seq.* (2011).

[22] *See, e.g.*, US-DEA-00005839; US-DEA-00005841; US-DEA-00005925; US-DEA-00005928; US-DEA-00005918; US-DEA-00005921; US-DEA-00005911; US-DEA-00005914; US-DEA-00005949; US-DEA-00005952; CAH_MDL2804_00958601; ABDCMDL00269679.

[23] *See* Press Release, *Washington: Pennsylvania Pharmaceutical Wholesaler Value Drug, Inc. to Pay $4,000,000 in Settlement*, DEA (June 25, 2014) *available at* https://www.dea.gov/press-releases/2014/06/25/pennsylvania-pharmaceutical-wholesaler-value-drug-inc-pay-4000000; Press Release, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act*, Justice Department Documents and Publications (Dec. 23, 2016), *available at* https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act; *Feds: McKesson agrees to pay $150M in pill shipment case*, U.S. News & World Report (Jan. 17, 2017), *available at* https://www.usnews.com/news/business/articles/2017-01-17/feds-mckesson-agrees-to-pay-150m-in-pill-shipment-case.

A. The DEA's suspicious order monitoring regulation and policies have been and remain vague.

Based on my experience, DEA's suspicious order monitoring regulation and policies were vague, leaving registrants with discretion in developing their own suspicious order monitoring programs.

1. Identifying potentially suspicious orders

The federal regulation states that the registrant must "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[24] The only codified information about how to identify "suspicious orders" is that "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[25] This definition hardly provides any clarity at all. What constitutes an order of unusual size? How are registrants to establish a normal pattern? And what kind of deviation from that pattern is considered substantial? What level of frequency is considered unusual?

Based on my experience at DEA, these terms were never clarified or explained in greater detail. Registrants were left to determine the meaning of these terms on their own and to report what *they* considered unusual. The effective design of a suspicious order monitoring system was subjective and left to the discretion of the registrant.[26] While the DEA provided several

[24] 21 C.F.R. § 1301.74(b).

[25] *See id.*

[26] *See* Feb. 28, 2019 Dep. of Kyle Wright at 71:1-8 (stating that DEA "did not dictate the criteria … for identifying excessive purchases"); *id.* at 195:22-196:18 (deciding if a volume increase is enough to make an order suspicious is "a judgment call by the manufacturer based upon their data");

See Mar. 15, 2019 Dep. of Demetra Ashley at 89:5-22 (stating that designing a suspicious order monitoring system is within the distributors' discretion, and that whether the system is effective is a subjective determination); *id.* at 246:4-247:1 (whether an order meets suspicious criteria varies from situation to situation); *id.* at 26:16-22 ("Q: Does the regulation tell -- provide guidance as to what constitutes an order of unusual size? A: No. Q: Does the regulation provide guidance as to what constitutes an order of unusual frequency? A: No."); *id.* at 147:1-7 ("Q: … So how much of a deviation would make it unusual? A: That would be determined by the distributor or the manufacturer. Q: So is there any threshold for determining whether a deviation is unusual? A: Not that the DEA sets, no."); *id.* at 88:2-10 ("Q: To your knowledge, is there a particular formula or algorithm that is required for a legally compliant system? … A: To my knowledge, there is not.");

suggestions and ideas about factors a registrant might take into consideration when designing a system, they required few. Orders can be reviewed through an automated system, or manually.[27] There is no list of characteristics, capabilities, or functions that a compliant suspicious order monitoring system must have, nor is there any requirement that a registrant must have written policies and procedures with respect to suspicious order monitoring.[28] Registrants largely have been left to figure out for themselves what would work best for their company, and to tweak their systems over time to account for new patterns, technologies, customers, or trends.[29]

Indeed, as noted by the Energy and Commerce Committee, "[n]either federal regulations nor the DEA . . . require distributors to use any particular method or system to flag those orders. As a result, individual distributors have designed and implemented their own unique detection systems to flag suspicious orders . . ." [30] Even Plaintiffs' expert James E. Rafalski has

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See Apr. 17, 2019 Dep. of Thomas Prevoznik at 179:22-180:11 ("Q: Now, does the DEA agree that there's more than one way to design and operate a system that can identify and report suspicious orders? A: Yes. Q: And there's no single feature that makes a suspicious order monitoring system compliant, correct? A: Correct. Q: And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A: Correct."); *Id*. at 183:1-12 ("Q: … [Y]ou and I looking at the same data, sometimes, not always, may come to different conclusions, as to whether an order is suspicious. Is that possible? … A: That is possible.");

See Apr. 26, 2019 Dep. of Joseph Rannazzisi at 120:1-4 (stating that "[i]t's up to the -- the distributor or the manufacturer, distributor to make a decision what information they will use to determine suspicious orders.").

[27] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 180:12-15 ("Q: Does it matter to the DEA whether a registrant reviews orders manually or uses an automated system? A: No, it doesn't matter.");

See Mar. 15, 2019 Dep. of Demetra Ashley at 88:11-89:4 ("Q: To your knowledge, does a legally compliant system need to be automated? A: No, it does not. Q: Does it need to be manual, i.e., the opposite of automated? … A: It's not specific. There's no direction on how to do it. Q: Are there particular methods of investigation that are required in order for a system to be legally compliant? A: Yes. Q: What are they? A: The method would be to -- as it's outlined in the regulation, to take a look at the order, make a determination if it's deviating from what's usual. I mean, how you do it, it can be manual or automatic, but it's just that it needs to be done.").

[28] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 358:21-359:1 ("Q: Does it say anywhere in the relevant regulations that registrants are required to have a written policy with respect to suspicious order monitoring? A: No.").

[29] *See id*. at 180:7-10 ("Q: And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A: Correct.").

See Mar. 15, 2019 Dep. of Demetra Ashley at 310:8-9 ("Q: Now, I'm correct in stating that the statute and reg does not tell them how to do their job, the registrants, correct? A: That's correct."); *id*. at 286:22-287:1 ("Q: You didn't tell them how to make their suspicious order monitoring system, did you? … A: We did not tell them how to make their suspicious order monitoring system.").

[30] *See Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, Energy & Commerce Committee Report, U.S. House of Representatives (Dec. 19, 2018) ("Dec. 19, 2018 Energy & Commerce Committee Report") at 180, *available at* https://republicans-energycommerce.house.gov/wp-content/uploads/2018/12/Opioid-Distribution-Report-FinalREV.pdf.

acknowledged that "Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ("SOMS"), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence efforts are required when investigating an order after it is identified as suspicious."[31] And this ambiguity is widely recognized by DEA employees, and even the DEA itself.[32] Accordingly, the compliance processes, metrics, and/or algorithms applied in the expert reports of Craig McCann and Lacey Keller are not the only steps that a company could have used to identify potentially suspicious orders.

The DEA has provided limited guidance to manufacturers about how to comply with the suspicious order monitoring regulation.[33] In fact, the 2007 Dear Registrant letter from Joseph Rannazzisi was the *only* written industry-wide guidance provided by DEA to manufacturers.[34] The

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[31] *See* Apr. 15, 2019 Expert Report of James Rafalski at 12-13.

[32] *See* Feb. 28, 2019 Dep. of Kyle Wright at 71:1-8 (stating that DEA "did not dictate the criteria … for identifying excessive purchases"); *id.* at 195:22-196:18 (deciding if a volume increase is enough to make an order suspicious is "a judgment call by the manufacturer based upon their data");

See Mar. 15, 2019 Dep. of Demetra Ashley at 89:5-22 (stating that designing a suspicious order monitoring system is within the distributors' discretion, and that whether the system is effective is a subjective determination); *id.* at 246:4-247:1 (whether an order meets suspicious criteria varies from situation to situation); *id.* at 26:16-22 ("Q: Does the regulation tell -- provide guidance as to what constitutes an order of unusual size? A: No. Q: Does the regulation provide guidance as to what constitutes an order of unusual frequency? A: No."); *id.* at 147:1-7 ("Q: So how much of a deviation would make it unusual? A: That would be determined by the distributor or the manufacturer. Q: So is there any threshold for determining whether a deviation is unusual? A: Not that the DEA sets, no."); *id.* at 88:2-10 ("Q: To your knowledge, is there a particular formula or algorithm that is required for a legally compliant system? … A: To my knowledge, there is not.");

See Apr. 17, 2019 Dep. of Thomas Prevoznik at 179:22-180:11 ("Q: Now, does the DEA agree that there's more than one way to design and operate a system that can identify and report suspicious orders? A: Yes. Q: And there's no single feature that makes a suspicious order monitoring system compliant, correct? A: Correct. Q: And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A: Correct."); *id.* at 183:1-12 ("Q: [Y]ou and I looking at the same data, sometimes, not always, may come to different conclusions as to whether an order is suspicious. Is that possible? … A: That is possible.");

See Apr. 26, 2019 Dep. of Joseph Rannazzisi at 120:1-4 (stating that "[i]t's up to the -- the distributor or the manufacturer, distributor to make a decision what information they will use to determine suspicious orders.").

[33] *See* Feb. 28, 2019 Dep. of Kyle Wright at 192:1-6 ("Q: During the time period that you were involved in the distributor initiatives, are you aware of any guidance the DEA provided to manufacturer registrant regarding Suspicious Order Monitoring? A: Specifically, no."); *id*. at 193:5-10 ("Q: As you sit here today, can you remember any guidance whatsoever that the DEA provided to manufacturer registrants regarding their obligations under the Suspicious Order Monitoring regulation? A: No.").

[34] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 305:17-22 ("Q: Since 2007 and the letter from Joe Rannazzisi, has the DEA provided manufacturers with any further written guidance regarding the obligation to monitor suspicious